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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,551	PARIKH ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,19-24,28,29 and 39-58* is/are pending in the application.

4a) Of the above claim(s) *1-3,19-24,28,29 and 39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is a supplemental Office action to the action mailed 26 September 2006. Applicant's representative called to indicate that a portion of the text at page 7 appeared to be missing. The Examiner agrees and a new Office action, with period for response, is being issued.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 August 2006 has been entered.

Applicant's response of 22 August 2006 has been received and entered. Claims 44, 47 and 52-53 have been amended and claims 57-58 have been added. Claims 1-3, 19-24, 28-29, 39-58 are currently pending. Claims 1-3, 19-24, 28-29 and 39-43 are withdrawn as they are directed to an invention nonelected with traverse in the reply filed on 26 April 2004. Claims 44-58 are under examination in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 22 August 2006 have been fully considered but are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 57 requires "therapeutically effective amounts" of gastrin/CCK receptor ligand and EGF receptor ligand. However, the claim fails to indicate what the agents are to be therapeutic for. Based on how the agents are to be used, the amounts which are intended could be very different. Since it is not clear what amounts are intended, the claims are indefinite.

Claim 58 indicates that the therapeutically effective amount is "20-500 micrograms per kilogram body weight". However, this type of recitation, which is dependent on some outside variable (i.e. body weight of the patient receiving the agent) is indefinite it is conditional without knowing the conditions. Additionally, since the

ligand is in a vial (or container of sorts), it would be in an absolute amount or concentration, where as the limitation recited in the claim is a dosage dependent on the patient to which the ligand is being administered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-58 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Conteas et al. (Proc. Soc. Exp. Biol. Med. 184(3): 307-311, 1987) for the reasons of record as applied to claims 44-56 in the previous Office action(s).

As stated previously, Conteas et al. teach the administration of gastrin and EGF, either alone or in combination (see page 308, column 1, lines 12-16). The gastrin and EGF were procured from Peninsula Laboratory and Collaborative Research, respectively. Therefore, it would be fair to conclude that the gastrin and EGF were in vials for shipment and were in close proximity to one another at some point in time (i.e. in the refrigerator or in a cabinet – together in a refrigerator or a cabinet could be considered a "container"). This would consititute a "kit" because the two components were together for use alone or in combination.

Conteas et al. is silent as to whether the gastrin and/or EGF were lyophilized or hydrated. However, it is standard procedures for biological agents to be shipped in a lyophilized form because they are usually more stable. It is also common for biological agents to be shipped in a sterile aqueous buffer. Conteas et al. does not indicate the form in which the gastrin and EGF were obtained, but it would have been *prima facie obvious* for them to be either as lyophilized powders, which could be rehydrated using a sterile buffer or water, or for them to have been in a buffer solution to begin with. If the gastrin and EGF were obtained in a lyophilized form, it would have been prima facie obvious to have included a buffer solution with the agents for rehydrating them for use. This buffer, be it water or saline or some other appropriate buffer, would also be expected to be sterile since the agents are biological agents and would be administered as such, requiring the composition to be sterile. As stated in the instant specification, pharmaceutical formulations are old and well known in the art (see Remington's *Pharmaceutical Sciences*, cited at page 11 of the specification).

The art of Conteas et al. does not indicate what form the gastrin and EGF were in, or whether a buffer was also present with the biological agents. However, Conteas et al. does teach that the two agents could be administered alone or together with therapeutic applications. The instant claims are merely directed to the same two biological agents of the prior art, in a box together, including a buffer to rehydrate the agents if they are in a lyophilized form. Further included in the claims are instructions for an intended use. These recitations do not physically change the biological agents which are known in the art and used by skilled artisans routinely. The inclusion of the

printed material does not change the nature of the biological agents of the claims. Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. In re Ngai, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (combining printed instructions and an old product into a kit will not render the claimed invention nonobvious even if the instructions detail a new use for the product). In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability).

In so far as claim 46 may (or may not) encompass the gastrin and EGF in combination (i.e. in the same vial, mixed together), this embodiment would have been prima facie obvious in view of Conteas et al. because Conteas teaches that the gastrin and EGF could be administered in combination. If they can be administered in combination, it would have been *prima facie obvious* to have them in combination prior to administration, i.e. in the same container, mixed together. Conteas et al. may anticipate the claims if when the two biological agents were administered, they were placed in the same syringe or other device for the administration. Further, if one were administering the two biological agents to a patient for a particular purpose, it is common to include the biological agents into an i.v. bag for intravenous administration. In this situation, the limitations of the claims would also be met.

Applicant argues that Conteas provides no suggestion of a kit including ligands that are purified enough to be suitable for administration to a human subject (see page 10 of the response). Applicant's argument has been considered, but is not persuasive.

Conteas et al. clearly teach gastrin and EGF, which appear to be sterile considering they were obtained from pharmaceutical companies, and the fact that they were used together would imply the presence of a "kit". There is no indication that the pharmaceutical compositions of gastrin and EGF were not acceptable for administration to a human, absent evidence to the contrary. Applicant alleges that the gastrin and/or EGF may only be research grade, and therefore, would not meet the limitations of the claims. Applicant's argument has been considered, but is not persuasive. Applicant has provided no evidence to support the assertion that the gastrin and/or EGF of Conteas would not have been suitable for administration to a human or that the gastrin and/or EGF of Conteas was only "research grade".

In the event that the gastrin and/or EGF of Conteas was not at a purity level that would make it suitable for administration to a human, it would have been obvious to select a higher grade gastrin and/or EGF because Conteas teach that the coadministration of these two growth factors is beneficial to proliferation of IEC cells, and use of these factors in vivo would necessitate the use of a suitable grade of gastrin and EGF for this purpose. Therefore, a kit comprising EGF and gastrin, wherein the ligands are suitable for administration to a human patient would have been *prima facie* obvious, absent evidence to the contrary.

New claim 58 recites "wherein the therapeutically effective amount of gastrin/CCK receptor ligand is 20-500 micrograms per kilogram body weight", however, whether an amount is therapeutically effective or not is not a limitation on the composition of the kit, but rather an inherent property of the compound/composition

itself. Since the claims are to a kit, and not a method of administering, this limitation places no material limitations on the composition itself.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 52 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of U.S. Patent No. 6,288,301. Although the conflicting claims are not identical, they are not patentably distinct from each other because the recitation of "a kit" does not distinguish the pharmaceutical composition of the instant claim from the pharmaceutical composition of the patented claim. A recitation of intended use does not physically limit the composition being claimed, and

therefore the claims encompass the same compositions, absent evidence to the contrary.

Applicant argues that claim 7 of '301 is not directed to a kit, but to a pharmaceutical composition. Applicant's argument has been fully considered, but is not persuasive. The rejection is an obviousness-type double patenting rejection. The pharmaceutical composition comprising all of the elements that are individually packaged in the kit, wherein the intention is to mix all of the elements together are clearly obvious over one another. Applicant argues that claim 7 of the '301 patent does not recite the specific species gastrin and EG1-53, and therefore, cannot render claim 52 obvious. This argument is not persuasive, because the disclosure of '301 clearly indicates that gastrin is a gastrin/CCK receptor ligand and EG1-53 is an EGF ligand and are therefore, clearly within the metes and bounds of the patented claim. A patent to the instant claim would result in an unjustified or improper timewise extension of the "right to exclude" granted by a patent.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud